

Message Text

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E.O. 11652: N/A

TAGS: TBIO, TPHY, OSCI, EG, USEGJC

SUBJECT: DHEW/PHS/FDA/SFCP - NEW AGREEMENT 03-621-F, "A COURSE
IN REGULATORY ANALYSIS" - JOINT WORKING GROUP ON MEDICAL COOPERATION

REF: STATE A-1383

1. SUBJECT AGREEMENT BETWEEN FOOD AND DRUG ADMINISTRATION AND
MINISTRY OF HEALTH, GOVERNMENT ORGANIZATION FOR DRUGS,
CHEMICALS, AND MEDICAL APPLIANCES, DRUG RESEARCH AND CONTROL
CENTER, TRANSMITTED REFAIR MARCH 3, 1975. EQUIPMENT NEEDED TO
CONDUCT COURSE MUST BE SHIPPED END OF MARCH. IN THE EVENT AGREEMENT
NOT SIGNED PRIOR TO SHIPPING DATE, REQUEST EMBASSY CONTACT
DR. A. K. MAZEN, FIRST UNDERSECRETARY, MINISTRY OF HEALTH,
OBTAIN ADVANCE APPROVAL AND CABLE CONCURRENCE IN PRINCIPLE
TO FDA. THIS COURSE IS ELEMENT UNDER MEDICAL COOPERATIVE JWG.

2. PERTINENT PORTION OF AGREEMENT FOLLOWS VERBATIM:

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DESCRIPTION OF PROJECT PLAN

THE COURSE IN REGULATORY ANALYSIS SHALL BE COMPRISED OF FOUR SEGMENTS: GENERAL CONSIDERATIONS, DRUG ANALYSIS, PESTICIDE RESIDUE ANALYSIS AND FUNGAL TOXIN ANALYSIS. THE COURSE IS TO BE HELD IN CAIRO, EGYPT, FOR A FIVE WEEK PERIOD BEGINNING SATURDAY, APRIL 12, 1975. DAILY INSTRUCTION WILL LAST APPROXIMATELY EIGHT HOURS. THE WORKING WEEK, SATURDAY, APRIL 12, 1975, THROUGH WEDNESDAY, APRIL 16, 1975, WILL BE DEVOTED TO THE GENERAL CONSIDERATIONS SEGMENT OF THE COURSE AND WILL COMPRISE BRIEF PRESENTATIONS ON THE FUNDAMENTALS OF ANALYSIS, MEASUREMENT, AND AUTOMATED DATA COLLECTION AND HANDLING. THE REMAINING THREE SEGMENTS OF THE COURSE WILL BE RUN SEPARATELY, CONCURRENTLY, AND WITH DIFFERENT STUDENT POPULATIONS AND INSTRUCTORS. THEY WILL COMMENCE ON SATURDAY, APRIL 19, 1975, AND THEIR RESPECTIVE DURATIONS SHALL BE AS FOLLOWS: DRUG ANALYSIS, THREE (3) WEEKS; PESTICIDE RESIDUE ANALYSIS, FOUR (4) WEEKS; AND FUNGAL TOXINS ANALYSIS, THREE (3) WEEKS. THE VARIOUS CLASS GROUPS WILL BE LIMITED IN NUMBER TO NO MORE THAN TEN (10) INDIVIDUALS WITH FORMAL TRAINING NO LESS THAN THE B.S. IN CHEMISTRY OR PHARMACY. SINCE IT IS ANTICIPATED THAT, (1) THE LATTER RESTRICTION WILL NOT SUFFICE TO LIMIT THE CLASS NUMBER TO TEN OR LESS; (2) LARGER CLASSES WILL HAVE A DETRIMENTAL EFFECT ON THE RESULTS OF THE COURSE; AND (3) A FIRST-COME-FIRST-SERVED POLICY DOES NOT SELECT CLASS PARTICIPANTS ON THE BASIS OF MERIT, AN ADDITIONAL REQUIREMENT FOR PARTICIPATION SHALL BE SET. PROSPECTIVE CLASS PARTICIPANTS MUST HAVE AT LEAST TWO YEARS PRACTICAL EXPERIENCE IN THE TOPIC THEY WISH TO PARTICIPATE IN (I.E., DRUG ANALYSIS, RESIDUE ANALYSIS, ETC.).

RESPONSIBILITIES OF DRUG RESEARCH AND CONTROL CENTER

THE DRCC SHALL MAKE AVAILABLE FOR THE COURSE APPROPRIATE LABORATORY FACILITIES, LECTURE HALLS, ETC., AND NECESSARY ITEMS OF SCIENTIFIC EQUIPMENT AND REAGENTS AS CAN BE PROCURED LOCALLY. THE DRCC SHALL PROVIDE FOR ANY LOCAL TRANSPORTATION OF INSTRUCTORS AND PARTICIPANTS, AND SHALL ASSUME RESPONSIBILITY FOR ANY EXPENSES INCURRED BY THE PARTICIPANTS. IT SHALL BE THE RESPONSIBILITY OF THE DRCC TO SELECT THE PARTICIPANTS FOR THE COURSE WITHIN THE RESTRICTIONS AS STATED IN NUMBER 2 ABOVE.

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RESPONSIBILITIES OF FDA

THE FDA WILL BE RESPONSIBLE FOR OBTAINING AND, IF NECESSARY, TRANSPORTING ITEMS (EQUIPMENT, REAGENTS, BOOKS, ETC.) REQUIRED FOR THE CONDUCT OF THE COURSE, AND NOT AVAILABLE TO DRCC. THIS WILL INCLUDE ARRANGEMENTS WITH THE U.S. NAVAL MEDICAL RESEARCH UNIT NO. 3 (NAMRU #3) FOR USE OF THEIR FACILITIES,

EQUIPMENT, AND SECRETARIAL SERVICES, IF REQUIRED. IT WILL BE THE RESPONSIBILITY OF THE FDA TO PROVIDE THE INSTRUCTORS FOR THE COURSE INCLUDING THEIR TRANSPORTATION, PER DIEM, AND MISCELLANEOUS EXPENSES WHILE EN ROUTE TO AND IN EGYPT.

3. FDA APPRECIATES EMBASSY ASSISTANCE EXPEDITING THIS AGREEMENT.
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